

SUPPLEMENTARY APPENDIX

Supplement to: Tess Petersen, Kerry Townsend, et al. High Adherence to All Oral Directly Acting Antiviral HCV Therapy Among Inner City Patient Population in Phase 2A Study

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**Supplemental Table 1: Seven Points Covered At Initiation of Directly Acting
Antiviral Therapy for Hepatitis C**

- Adherence measures were in order to correlate study outcomes with adherence after completion of study, and as such, would not affect participation/continuation in the study at any point
- Instruction regarding proper use of MEMS cap: Patients are to only open MEMS cap when ready to take dose and close MEMS cap following dose
- Patients instructed not to use a pill box for study drug
- Patient is to take her/his dose at exactly the same time each day
- Appropriate dosing of study drug reviewed with patients (1 tablet PO once daily (arm A), 2 tablets PO once daily (arm C), or 3 tablets PO once daily (arm B) with or without food
- Patients advised that it is OK to take dose (if forgotten), when she/he remembers within same day. Patients advised to not to double any doses (if dose forgotten until the next day)
- Patients reminded to bring Rx bottle to every visit

Adherence Baseline Questionnaire

Date: _____

Self Interviewer Both

Patient ID: _____

How Administered?

Study Visit: _____

The answers you give on this form will be used to plan ways to help other people who must take pills on a difficult schedule. Please do the best you can to answer all the questions. If you do not wish to answer a question, please draw a line through it. If you do not know how to answer a question, ask your study nurse to help. Thank you for helping in this important study.

INSTRUCTIONS: Please answer the following questions by placing a circle around the appropriate number response.

A. How sure are you that:

Please circle one response for each question.

	<u>Not at All Sure</u>	<u>Somewhat Sure</u>	<u>Very Sure</u>	<u>Extremely Sure</u>
1. You will be able to take all or most of the study medication as directed?	0	1	2	3
2. The medication will have a positive effect on your health?	0	1	2	3

B. The following questions ask about your social support.

Please circle one response for each question.

	<u>Very Dissatisfied</u>	<u>Somewhat Dissatisfied</u>	<u>Somewhat Satisfied</u>	<u>Very Satisfied</u>	
1. In general, how satisfied are you with the overall support you get from your friends and family members?	0	1	2	3	
	<u>Not At All</u>	<u>A Little</u>	<u>Somewhat</u>	<u>A Lot</u>	<u>Not Applicable</u>
2. To what extent do your friends or family members help you remember to take your medication?	0	1	2	3	4

C. People may miss taking their medications for various reasons. Here is a list of possible reasons why you may have missed taking any medications within the **past month**.

If you have **NOT** taken **any** medications within the **past month**, please

check this box and skip to Section **E**.

In the past month, how often have you missed taking your medications because you:

Please circle one response for each question.

	<u>Never</u>	<u>Rarely</u>	<u>Sometimes</u>	<u>Often</u>
1. Were away from home?	0	1	2	3
2. Felt hassled or inconvenienced by medicine?	0	1	2	3
3. Simply forgot?	0	1	2	3
4. Had too many pills to take?	0	1	2	3
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5. Felt worse when you took pills?	0	1	2	3
6. Did not want others to notice you taking medication?	0	1	2	3
7. Had a change in daily routine?	0	1	2	3
8. Felt like the drug was toxic/harmful?	0	1	2	3
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9. Fell asleep/slept through dose time?	0	1	2	3
10. Felt sick or ill?	0	1	2	3
11. Felt depressed/overwhelmed?	0	1	2	3
12. Had problem taking pills at specified times (with meals, on empty stomach, etc.)?	0	1	2	3
13. Ran out of pills?	0	1	2	3
14. Felt like treatment was working?	0	1	2	3

D. When was the last time you missed taking any of your medications? Check one box.

- Within the past **week**
- 1-2 **weeks** ago
- 2-4 **weeks** ago
- 1-3 **months** ago
- More than 3 **months** ago
- Never** skip medications or **not applicable**

E. In the past week how often did you:

Please circle one response for each question.

	<u>Never/ Rarely</u>	<u>Sometimes</u>	<u>Often</u>	<u>Mostly or Always</u>
1. Feel like you couldn't shake off the blues even with help from your family or friends?	0	1	2	3
2. Have trouble keeping your mind on what you were doing?	0	1	2	3
3. Feel that everything you did was an effort?	0	1	2	3
4. Have trouble sleeping?	0	1	2	3
5. Feel lonely?	0	1	2	3
6. Feel sad?	0	1	2	3
7. Feel like you just couldn't "get going"?	0	1	2	3

F. In the past month, how often have you:

Please circle one response for each question.

	<u>Never</u>	<u>Almost Never</u>	<u>Sometimes</u>	<u>Fairly Often</u>	<u>Very Often</u>
1. Been upset because of something that happened unexpectedly?	0	1	2	3	4
2. Felt unable to control the important things in your life?	0	1	2	3	4
3. Felt nervous and "stressed"?	0	1	2	3	4
4. Felt confident in your ability to handle your personal problems?	0	1	2	3	4
5. Felt that things were going your way?	0	1	2	3	4
6. Found that you could not cope with all the things that you had to do?	0	1	2	3	4
7. Been able to control irritations in your life?	0	1	2	3	4
8. Felt that you were on top of things?	0	1	2	3	4
9. Been angered because of things that happened that were outside of your control?	0	1	2	3	4
10. Felt problems were piling up so high that you could not overcome them?	0	1	2	3	4

4. Please check "Yes" or "No" for each question.

a. Yes No

**Have you ever used marijuana?
If you used this drug, have you used it within the past 6 months?**

Yes No

b. Yes No

**Have you ever used cocaine (powder, crack, or freebase)?
If you used this drug, have you used it within the past 6 months?**

Yes No

c. Yes No

**Have you ever used heroin?
If you used this drug, have you used it within the past 6 months?**

Yes No

d. Yes No

**Have you ever used amphetamines (speed)?
If you used this drug, have you used it within the past 6 months?**

Yes No

H. These last questions ask about your background.

1. **What is the highest level of education you have completed?** (check one)

- 11th grade or less
- High school graduate or GED
- 2 years of college / AA degree / Technical school training
- College graduate (BA or BS)
- Master's Degree
- Doctorate / medical degree / law degree

2. **What is (are) the most likely way(s) that you became infected with hepatitis C?** (check "Yes" or "No" for each question.)

a. Shared needles with a person who was Hepatitis C+

- Yes No

b. Shared straws (snorting) with a person who was Hepatitis C+

- Yes No

c. Blood transfusion or other medical procedure

- Yes No

d. Sex with a person who was Hepatitis C+

- Yes No

e. Don't know

- Yes No

f. Other (needle stick at work, etc.)

- Yes No

Please specify: _____

3. **Do you work for pay outside the home?** Yes No

4. **Do you have any children?** Yes No

If Yes, how many live with you? _____

4. People may miss taking their medications for various reasons. Here is a list of possible reasons why you may miss taking your medications. How often have you missed taking your medications because you: (Circle one response for each question.)

	Never	Rarely	Sometimes	Often
1. Were away from home?	0	1	2	3
2. Felt hassled or inconvenienced by medicine?	0	1	2	3
3. Simply forgot?	0	1	2	3
4. Had too many pills to take?	0	1	2	3
5. Felt worse when you took pills?	0	1	2	3
6. Did not want others to notice you taking medication?	0	1	2	3
7. Had a change in daily routine?	0	1	2	3
8. Felt like the drug was toxic/harmful?	0	1	2	3
9. Fell asleep/slept through dose time?	0	1	2	3
10. Felt sick or ill?	0	1	2	3
11. Felt depressed/overwhelmed?	0	1	2	3
12. Had problems taking pills at specified times (with meals, on empty stomach, etc.)?	0	1	2	3
13. Ran out of pills?	0	1	2	3
14. Felt like treatment was working?	0	1	2	3

SYNERGY ADHERENCE QUESTIONNAIRE: GROUP C

Date _____

Study ID _____

Study Visit _____

1. How many doses of GS-7977/GS-5885 (blue pill) have you missed since your last study visit? _____

2. How many doses of GS-9451 have you missed since your last study visit? _____

3. Since your last study visit, how often did you take your study medications with food? Check one.

- All of the time
- Most of the time
- About half of the time
- Some of the time
- Never

4. Some people find that they forget to take their pills on the weekend days. Did you miss any of your hepatitis C medications last weekend– last Saturday or Sunday?

- Yes
- No

5. When was the last time you missed any of your study medications? Check one.

- Within the past week
- 1-2 weeks ago
- 2-4 weeks ago
- 1-3 months ago
- Never skip medications or not applicable

6. People may miss taking their medications for various reasons. Here is a list of possible reasons why you may miss taking your medications. Have you ever missed taking your study medications because you: (Circle one response for each question.)

	Never	Rarely	Sometimes	Often
1. Were away from home?	0	1	2	3
2. Felt hassled or inconvenienced by medicine?	0	1	2	3
3. Simply forgot?	0	1	2	3
4. Had too many pills to take?	0	1	2	3
5. Felt worse when you took pills?	0	1	2	3

SYNERGY ADHERENCE QUESTIONNAIRE: GROUP C

6.	Did not want others to notice you taking medication?	0	1	2	3
7.	Had a change in daily routine?	0	1	2	3
8.	Felt like the drug was toxic/harmful?	0	1	2	3
9.	Fell asleep/slept through dose time?	0	1	2	3
10.	Felt sick or ill?	0	1	2	3
11.	Felt depressed/overwhelmed?	0	1	2	3
12.	Had problems taking pills at specified times (with meals, on empty stomach, etc.)?	0	1	2	3
13.	Ran out of pills?	0	1	2	3
14.	Felt like treatment was working?	0	1	2	3

SYNERGY ADHERENCE QUESTIONNAIRE: GROUP B

Date _____

Study ID _____

Study Visit _____

1. How many doses of GS-7977/GS-5885 (blue pill) have you missed since your last study visit? _____

2. How many doses of GS-9669 (white pills) have you missed since your last study visit? _____

3. Since your last study visit, how often did you take your study medications with food? Check one.

- All of the time
- Most of the time
- About half of the time
- Some of the time
- Never

4. Some people find that they forget to take their pills on the weekend days. Did you miss any of your hepatitis C medications last weekend– last Saturday or Sunday?

- Yes
- No

5. When was the last time you missed any of your study medications? Check one.

- Within the past week
- 1-2 weeks ago
- 2-4 weeks ago
- 1-3 months ago
- Never skip medications or not applicable

6. People may miss taking their medications for various reasons. Here is a list of possible reasons why you may miss taking your medications. Have you ever missed taking your study medications because you: (Circle one response for each question.)

	Never	Rarely	Sometimes	Often
1. Were away from home?	0	1	2	3
2. Felt hassled or inconvenienced by medicine?	0	1	2	3
3. Simply forgot?	0	1	2	3
4. Had too many pills to take?	0	1	2	3
5. Felt worse when you took pills?	0	1	2	3

SYNERGY ADHERENCE QUESTIONNAIRE: GROUP B

6.	Did not want others to notice you taking medication?	0	1	2	3
7.	Had a change in daily routine?	0	1	2	3
8.	Felt like the drug was toxic/harmful?	0	1	2	3
9.	Fell asleep/slept through dose time?	0	1	2	3
10.	Felt sick or ill?	0	1	2	3
11.	Felt depressed/overwhelmed?	0	1	2	3
12.	Had problems taking pills at specified times (with meals, on empty stomach, etc.)?	0	1	2	3
13.	Ran out of pills?	0	1	2	3
14.	Felt like treatment was working?	0	1	2	3